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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|-----------------|-------------|----------------------|----------------------|------------------|
| 09/557,907      | 04/21/2000  | Holly Horton         | 1530.0060004/EKS/EJH | 9397             |

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EXAMINER

WILSON, MICHAEL C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1632     |              |

DATE MAILED: 11/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                  |
|------------------------------|-------------------------------|------------------|
| <b>Office Action Summary</b> | Application No.               | Applicant(s)     |
|                              | 09/557,907                    | HORTON ET AL.    |
|                              | Examiner<br>Michael C. Wilson | Art Unit<br>1632 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 August 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-7,16-18,30-35,38-41,43,46-50,66,69,71-74,77,78 and 83-86 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3-7,16-18,30-35,38-41,43,46-50,66,69,71-74,77,78 and 83-86 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>21</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)               |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>19</u> | 6) <input type="checkbox"/> Other:  |

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-21-02, paper number 18, has been entered.

Claims 9-15, 19-22, 42, 44, 45, 67, 70 and 79-81 have been canceled. Claims 1, 3-7, 16-18, 30-35, 38-41, 43, 46-50, 66, 69, 71-74, 77, 78 and 83-86 are under consideration in the instant office action. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicant's arguments filed 8-21-02, paper number 20, have been fully considered but they are not persuasive.

### ***Claim Objections***

In claim 1, 66 and 78, "through operable association with" should be changed to --operably associated with--.

In claim 3, "in operable association with" should be changed to --operably associated with--.

In claims 16 and 17, "α" should be changed to --alpha--.

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In claim 18, --plasmid-- should be inserted after "said DNA".

***Claim Rejections - 35 USC § 112***

The rejection of claims 1, 3-7, 16-18, 30-35, 38-41, 43, 46-50, 66, 69, 71-74, 77, 78 and 83-86 under 35 U.S.C. 112, first paragraph, enablement, has been withdrawn in view of the amendments to the claims and in view of Example 6 which describes delivering plasmid DNA encoding IFN- $\alpha$  operably linked to a promoter intraperitoneally to a mouse having a tumor such that an increase in survival occurs (pg 124, lines 10-20).

The rejections of claims 1, 3-7, 16-18, 30-35, 38-41, 43, 46-50, 66, 69, 71-74, 77, 78 and 83-86 under 35 U.S.C. 112, second paragraph, have been withdrawn in view of the amendments to the claims and because plasmid can have a promoter as in claim 1 and other regulatory sequences as in claim 43.

1. Claims 16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 18 are indefinite because they are dependent upon a canceled claim. It appears that claims 16 and 18 should be dependent upon claim 1.

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***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 1, 3-7, 16-18, 30-35, 38-41, 43, 46-50, 66, 69, 71-74, 77, 78 and 83-86 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 164, 185, 189, 201, 202, 206, 207, 209, 210, 212, and 213 of copending Application No. 09/839574 in view of Dalgleish (1995, Cancer Surveys, Vol. 296, pg 289-320).

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The claims of '574 teach administering plasmid DNA encoding IFN- $\alpha$  into skeletal muscle or intraperitoneally to treat disease. The claims of '574 do not specifically require treating cancer. Treating disease in claims 201, 202 et al. of '574 is a genus to treating cancer as claimed in the instant invention. Using DNA at a concentration of 1-30 ng and salt at 20-300 mM as in '574 is an obvious species of the instant invention. However, Dalgleish taught treating cancer using IFN- $\alpha$ . Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administering plasmid DNA encoding IFN- $\alpha$  into skeletal muscle or intraperitoneally to treat disease as taught in '574 to treat cancer as taught by Dalgleish. One of ordinary skill in the art at the time the invention was made would have been motivated to use the method of '574 to treat cancer using IFN- $\alpha$  to reduce tumors.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1, 3-6, 16-18, 30-35, 38-41, 43 and 46-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48, 52, 57, 59, 61, 72, 74, 76, 77, 79, 81, 82 and 84 of copending Application No. 09/588655 in view of Dalgleish (1995, Cancer Surveys, Vol. 296, pg 289-320).

The claims of '655 teach administering plasmid DNA encoding IFN into heart muscle and obtaining activity of the protein. The claims of '655 do not specifically require treating cancer or that the IFN is IFN- $\alpha$ . Obtaining physiologically active expression of a protein as in claims 81, 82 and 84 of '655 is a genus to treating cancer as claimed in the instant invention. Administering

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DNA to the heart as in '574 is an obvious species of "muscle" as claimed in the instant invention. However, Dalgleish taught treating cancer using IFN- $\alpha$ . Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administering plasmid DNA encoding IFN into the heart and obtain activity of IFN claimed in '574 to treat cancer using IFN- $\alpha$  as taught by Dalgleish. One of ordinary skill in the art at the time the invention was made would have been motivated to use the method of '574 to treat cancer using IFN- $\alpha$  to reduce tumors.

This is a provisional obviousness-type double patenting rejection.

4. Claims 1, 3-7, 16-18, 30-35, 38-41, 43, 46-50, 66, 69, 71-74, 77, 78 and 83-86 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/028782. Although the conflicting claims are not identical, they are not patentably distinct from each other because they have the same limitations and are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Conclusion*

No claim is allowed.

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Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

